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EXAMINER	
DUNSTON, JENNIFER ANN	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,283	DERAND ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *4-10,14,16-20,26-33 and 36-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,11-13,15,21-25,34,35,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

JIC

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 2/10/2005 is acknowledged. Applicant's election of sub-species type (a) spacer, sub-species type (b) MRP1, and sub-species type (c) Kir6.2 is also acknowledged. The traversal is on the ground(s) that (i) the claims of Groups II-IV depend from claims of Group I, and thus the groups are not separable, (ii) the Office has not provided reasons and/or examples to support the restriction between groups, and (iii) the search of all of the claims would not be a serious search burden. This is not found persuasive because the groups are drawn to independent and distinct inventions for the reasons given on pages 2-5 of the Office action mailed 11/2/2004, even though claims may be written in dependent form. For example, Groups I and IV are related as product and process of use; however, the hybrid protein of Group I can be used in a materially different process such the determination of the crystal structure of the protein or the manufacture of antibodies. Further, the ion channel protein of Group I has a different chemical structure and functional activity than the polynucleotide of Group II or primers of Group III. Furthermore, the inventions of Groups I-IV have acquired separate status in the art as shown by their different classification. Although Groups II and III were assigned the same classification in the Office action mailed 11/2/2004, Group III can be further classified as class 536, subclass 24.33. Moreover, separate searches would need to be made of the non-patent literature and commercial sequence databases for each of the proteins of Group I and nucleic acids of Groups II and III. The searches for the groups are not coextensive in that each groups requires a separate search of the patent and non-patent literature and the commercial sequence databases. Each of the searches requires an extensive

analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. Therefore, searching more than one group would impose a serious search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-10, 14, 16-20, 26-33 and 36-44 are withdrawn from further consideration, as being drawn to a nonelected invention. An examination on the merits of claims 1-3, 11-13, 15, 21-25, 34, 35, 45 and 46 follows.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

Page 5, line 14 contains an amino acid sequence, FKYENE, that is not referred to by the use of a sequence identifier. Where the description or claims of a patent application discuss a sequence that is set forth in the Sequence Listing, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

In response to this office action, Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. The nature of the non-compliance did not preclude an examination of the elected invention on the merits, the results of which are presented below.

Specification

The abstract of the disclosure is objected to because it contains legal phraseology such as "said membrane protein" (e.g. page 26, lines 4 and 5) and "said membrane proteins" (e.g. page 26, lines 5-6). Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 25 is objected to because of the following informalities: the claim reads on non-elected inventions.

Claims 45 and 46 are objected to because of the following informalities: the claims recite the phrase "comprising at least." The phrase "at least" is redundant and should be deleted. The transitional phrase "comprising" is open language indicating that other components may be present in the kit. Appropriate correction is required.

Claim 45 is objected to because of the following informalities: it would be preferable to replace the slash between the terms "agonist" and "antagonist" with the word "or." Appropriate correction is required.

Claim 46 is objected to because of the following informalities: the recitation of "contaminant" and "pollutant" is redundant. The Encarta® World English Dictionary, North American Edition defines the term "pollutant" as something causing pollution: something that pollutes, for example, chemicals or waste products that contaminate the air, soil, or water. Thus, it would be preferable to delete either "contaminant" or "pollutant." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 11-13, 15, 21-24, 34, 35, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a set of hybrid proteins consisting essentially of a fusion of a membrane protein with an ion channel that is not naturally coupled to said membrane protein. Claims 2 and 3 further require the presence of a spacer between the membrane protein and ion channel, but do not further limit either the membrane protein or ion channel. Claims 11-13 and 15 further limit the membrane protein. Claim 11 broadly limits the membrane protein to a transporter. Claim 12 limits the transporter of claim 11 to an ABC transporter, and claim 12 limits the ABC transporter to one selected from the MRP class. Claim 15 limits the transporter to MRP1. Although claims 11-13 and 15 progressively narrow the scope of the claims with regard to the membrane protein, they do not further limit the ion channel, and thus encompass hybrid proteins with any ion channel. Claims 21-24 further limit the ion channel. Claim 21 broadly limits the ion channel to a potassium channel. Claim 22 limits the potassium channel to an ATP-sensitive potassium channel. Claim 23 limits the ATP-sensitive potassium channel to a

channel from the Kir family, and claim 24 limits the channel to Kir6.2. Although claims 21-24 progressively narrow the scope of the claims with regard to the ion channel, they do not further limit the membrane protein, and thus encompass hybrid proteins with any membrane protein. The rejected claims thus comprise a set of hybrid proteins that encompass the fusion of any membrane protein to any ion channel.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification envisions the use of the hybrid proteins as electrical sensors of membrane protein (e.g. receptor or transporter) activity such that the receptor or transporter occupancy by a ligand is transferred to the ion channel and transduced into an electrical signal that is detected by standard electrophysiological techniques (e.g. page 1, lines 3-13; page 3, lines 1-5). The specification envisions the use of membrane proteins such as receptors, active transporters and passive transporters such as neurotransmitter receptors, hormone receptors, drug receptors, olfactive receptor, and heavy metal transporters (e.g. page 3, lines 24-28). Regarding the ion channel, the specification envisions the use of channels which have one or several of the following properties: they are coupled with a receptor/transporter in a physiological manner, they are encoded by a very small gene and easily handled by molecular biology, their gating behavior is straightforward and they are regulated and blocked by a simple ligand, which allows testing of the hybrid protein by simple electrophysiological assays (e.g. page 4, lines 1-7). Furthermore, the specification envisions the use of functional derivatives of

membrane proteins and ion channels (e.g. pages 4-5). The specification describes fusions of the Kir6.2 ion channel to the following ABC transporter proteins not normally associated with Kir6.2: MRP1, YCF1, and Mdr1 (e.g. Table 1). No description is provided of the fusion of any other ion channel with any other membrane proteins. No description is provided of the genus of membrane proteins that are normally coupled with ion channels. A representative number of species of membrane proteins that are normally coupled with ion channels are not disclosed, and no structural/functional relationship is provided to allow one of skill in the art to envision a representative number of members of this genus. No description is provided of the genus of ion channel proteins that are normally coupled with membrane proteins. A representative number of species of ion channels are not disclosed, and no structural/functional relationship is provided to allow one of skill in the art to envision a representative number of members of this genus.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of a few hybrid proteins. The results are not necessarily predictive of other hybrid proteins comprising any membrane protein and any ion channel such that the hybrid protein is capable of functioning as an electrical sensor. Thus, it is impossible for one to extrapolate from the few examples described herein those hybrid proteins that would necessarily meet the structural/functional characteristics of the rejected claims. Furthermore, the prior art does not appear to offset the deficiencies of the instant specification in that the art of record does not describe a set of hybrid proteins that provide sufficient structural/functional information for one of skill in the art to envision other members of the genus.

Given the very large genus of hybrid proteins encompassed by the rejected claims, and given the limited description provided by the prior art and specification, the skilled artisan would not have been able to envision a sufficient number of specific embodiments that meet the limitations of the claims to describe the broadly claimed genus. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those functional hybrid proteins that satisfy the limitations of the claims. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 1-3, 11-13, 15, 21-24, 34, 35, 45 and 46.

Claims 1-3, 11-13, 15, 21-25, 34, 35, and 45-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The claims are drawn to a set of hybrid proteins consisting essentially of a fusion of a membrane protein with an ion channel that is not naturally coupled to said membrane protein. Claims 2 and 3 further require the presence of a spacer between the

membrane protein and ion channel, but do not further limit either the membrane protein or ion channel. Claims 11-13 and 15 further limit the membrane protein. Claim 11 broadly limits the membrane protein to a transporter. Claim 12 limits the transporter of claim 11 to an ABC transporter, and claim 12 limits the ABC transporter to one selected from the MRP class. Claim 15 limits the transporter to MRP1. Although claims 11-13 and 15 progressively narrow the scope of the claims with regard to the membrane protein, they do not further limit the ion channel, and thus encompass hybrid proteins with any ion channel. Claims 21-24 further limit the ion channel. Claim 21 broadly limits the ion channel to a potassium channel. Claim 22 limits the potassium channel to an ATP-sensitive potassium channel. Claim 23 limits the ATP-sensitive potassium channel to a channel from the Kir family, and claim 24 limits the channel to Kir6.2. Claim 25 further limits the hybrid proteins to SEQ ID NOS: 1-11. Although claims 21-25 progressively narrow the scope of the claims with regard to the ion channel, they do not further limit the membrane protein, and thus encompass hybrid proteins with any membrane protein. The rejected claims thus comprise a set of hybrid proteins that encompass the fusion of any membrane protein to any ion channel.

The nature of the invention is complex in that the hybrid protein consisting essentially of a membrane protein and an ion channel protein must be properly folded and inserted into a lipid membrane (e.g. the plasma membrane of a cell or a lipid vesicle). Furthermore, the functionality of the hybrid protein depends upon the functional coupling of membrane protein activity to gating of the ion channel such that the ion channel activity is only dependent upon the active state of the membrane protein.

Breadth of the claims: The claims are incredibly broad in that they encompass hybrid proteins of any membrane protein and any ion channel. The breadth of the claims greatly exacerbates the complexity of the invention.

Guidance of the specification and existence of working examples: The specification envisions the use of the hybrid proteins as electrical sensors of membrane protein (e.g. receptor or transporter) activity such that the receptor or transporter occupancy by a ligand is transferred to the ion channel and transduced into an electrical signal that is detected by standard electrophysiological techniques (e.g. page 1, lines 3-13; page 3, lines 1-5). The specification envisions the use of membrane proteins such as receptors, active transporters and passive transporters such as neurotransmitter receptors, hormone receptors, drug receptors, olfactive receptor, and heavy metal transporters (e.g. page 3, lines 24-28). Regarding the ion channel, the specification envisions the use of channels which have one or several of the following properties: they are coupled with a receptor/transporter in a physiological manner, they are encoded by a very small gene and easily handled by molecular biology, their gating behavior is straightforward and they are regulated and blocked by a simple ligand, which allows testing of the hybrid protein by simple electrophysiological assays (e.g. page 4, lines 1-7). The specification teaches how to make the following hybrid proteins, which meet the structural limitations of the claims: MRP1-Kir6.2, YCF1-Kir6.2, MRP1-Kir6.2ΔC36, YCF1-Kir6.2ΔC36, MRP1-Kir6.2[KR370AA], MRP1-Kir6.2HA, YCF1-Kir6.2ΔC36HA, YCF1-Kir6.2ΔC36HA-FCYENE, and Mdr1-Kir6.2 (e.g. page 6, lines 18-25; Table 1; Example 1).

The working examples demonstrate that MRP1-Kir6.2 fusion proteins are capable of inserting as functional channels into the plasma membrane (e.g. Example 3). Further, the

working examples teach that YCF1-Kir6.2 is inoperable in that no detectable currents were produced (e.g. Example 4). The specification suggests that the YCF1-Kir6.2 fusion protein may not produce a current because of any number of reasons, including missfolding of the protein, incorrect addressing of the protein (e.g. to the plasma membrane), or impaired channel gating (e.g. page 20, ones 22-27). However, it was demonstrated that removal of the ER retention signal in the YCF1-Kir6.2ΔC36 hybrid protein did produce detectable currents (e.g. page 20, lines 26-31). No working examples are provided for any other fusion proteins. For example, there is no evidence that the Mdr1-Kir6.2 hybrid protein is properly folded, trafficked and inserted into the membrane such that a functional ion channel is formed. With regard to using the ion channel current to detect the binding of a ligand to the transporter protein, the working examples teach the ability of MRP1-Kir6.2 and MRP1-Kir6.2KR370AA to sense intracellular ADP changes in a dose-dependent manner (e.g. page 19, lines 9-20; Figures 6B and 6C). However, there were no obvious differences in activity between Kir6.2ΔC36 and MRP1-Kir6.2 (e.g. page 20, lines 5-8; Figure 6). As stated in the specification, "it may be speculated that MRP1, in contrast to SUR, cannot either sense or transmit to Kir6.2 internal nucleotides variations within the range of concentrations tested" (See page 20, lines 5-8). Thus, the specification does not teach how to use the fusion proteins described in SEQ ID NOS: 1-11 as electrical sensors and does not teach how to make and use hybrid proteins commensurate in scope with the claimed invention.

Predictability and state of the art: At the time the invention was made, the molecular identity of Kir6.1 and Kir6.2, ATP-sensitive potassium channels, was elucidated; however, the mechanism whereby the binding of ADP to the sulfonylurea receptor (SUR) is transduced to the

Kir6.2 subunit was not known in the art (Baukrowitz et al. European Journal of Biochemistry, Vol. 267, pages 5842-5848, 2000; e.g. pages 5842-5843, Molecular Architecture of K_{ATP}; page 5846, Conclusions). Without an understanding of the mechanism by which ligand binding is coupled to channel activity, it would be unpredictable to make a biosensor consisting essentially of the fusion of a membrane protein with an ion channel which is not naturally coupled to said membrane protein. Further, Baukrowitz et al teach that a mutant of Kir6.2 lacking the 26 C-terminal residues forms functional channels in the absence of SUR (e.g. page 5844, left column, first full paragraph). Moreover, Baukrowitz et al teach that ADP in physiological conditions (i.e. the presence of millimolar concentrations of Mg^{2+}) acts as an inhibitor of Kir6.2 through the action of SUR (e.g. page 5844, Antagonism of ATP Inhibition by ADP and ATP Acting at the SUR). Thus, the similar activities of Kir6.2ΔC36 and MRP1-Kir6.2 disclosed in the instant specification suggest that MRP1 is unable to transduce a signal to the Kir6.2 subunit, and thus the fusion protein does not function as a biosensor.

Amount of experimentation necessary: Given the lack of guidance in the specification and prior art with regard to how to make and use a hybrid protein biosensor consisting essentially of a membrane protein and an ion channel which is not naturally coupled to said membrane protein, the quantity of experimentation in this area is very large. The skilled artisan would have to conduct a large number of trial and error experiments to learn the which membrane proteins can be coupled to which ion channels to allow the transduction of a signal from the membrane protein to the ion channel. First, the skilled artisan would have to isolate the nucleic acid sequence encoding a membrane protein. Next, the skilled artisan would have to isolate the nucleic acid sequence encoding an ion channel and make a fusion construct with the membrane

protein. To determine if the hybrid protein is capable of functioning as a biosensor, one would need to express the protein and test the expressed protein in the context of a whole cell or purify the protein and insert it into a lipid bilayer *in vitro*. Once the biosensor is assembled, one would have to screen a library of potential ligands for the ability to interact with the membrane protein such that the membrane protein transduces a signal to the ion channel, where the electrical potential across the membrane changes to indicate ligand interaction. If unsuccessful, which is likely given the unpredictable nature of the invention, one would need to modify the hybrid protein (e.g. change the linker sequence between the membrane protein and ion channel) or start over (e.g. use a different membrane protein or ion channel). This would require a large amount of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, claims 1-3, 11-13, 15, 21-25, 34, 35, and 45-46 are not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11, 12, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Vankeerberghen et al (Biochemistry, Vol. 38, pages 14988-14998, 1999; see the entire reference).

Vankeerberghen et al teach a hybrid protein consisting essentially of the cystic fibrosis transmembrane conductance regulator (CFTR) and P-glycoprotein (MDR1), both of which are members of the ATP binding cassette (ABC) transporter family (e.g. page 14988, left column; Figure 2). Further, CFTR is a chloride ion channel (e.g. page 14994, section 3.1). Further, Vankeerberghen et al teach a host cell expressing said hybrid protein, wherein the hybrid protein is incorporated into the membrane as evidenced by chloride current (e.g. page 14991, section 2; Figures 5-7). Thus, Vankeerberghen et al necessarily teach a hybrid protein consisting essentially of the fusion of an ABC transporter with an ion channel which are not naturally coupled, and a cell comprising said hybrid protein, wherein the hybrid protein is incorporated into the membrane.

Claims 1, 21-24, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Takano et al (Journal of Physiology, Vol. 512, pages 395-406, 1998; see the entire reference).

Takano et al teach a hybrid protein consisting essentially of Kir6.1 and Kir6.2, both of which are ATP-sensitive potassium channels of the Kir family (e.g. page 395, left column; page 396, Molecular biological experiments; Figure 5). Further, Takano et al teach a host cell expressing said hybrid protein, wherein the hybrid protein is incorporated into the membrane as evidenced by single-channel conductances of the chimeric channels (e.g. page 396, Transfection, Patch clamp experiment; Figures 6-9). Thus, Takano et al necessarily teach a hybrid protein

consisting essentially of the fusion of a membrane protein with a Kir6.2 ATP-sensitive potassium channel, and a cell comprising said hybrid protein, wherein the hybrid protein is incorporated into the membrane.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

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Jennifer Dunston
Examiner
Art Unit 1636

jad

TERRY MCKELVEY
PRIMARY EXAMINER